

Appl. No. 10/810,940
Docket No. 9191M
Amdt. dated October 29, 2007
Reply to Office Action mailed on September 12, 2007
Customer No. 27752

REMARKS**Claim Status**

Claims 1-7 and 9-19 are pending in the present application. Claim 8 was previously canceled without prejudice. No additional claims fee is believed to be due.

Claim 1 has been amended to recite a range of from about 0.01% to about 15% of a fiber agent selected from the group consisting of ingestible dextrin, purified wood cellulose, psyllium, and mixtures thereof. Support for the amendment to the upper limit of the range is found in original Claim 3.

Claims 14-19 have been withdrawn as a result of an earlier restriction requirement. It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §102

Claims 1, 3-4 and 9 are rejected under 35 USC § 102(a) and 102(e) as being anticipated by US Patent Application 2002/0131990 to Barkalow et al. ("Barkalow"). The Examiner states that Barkalow et al. discloses an edible film composition comprising bulk filler agents, film forming agents, plasticizing agents and flavoring agents wherein the bulk fibers may be wood cellulose. The Examiner also states that the Applicants claim "safe and effective amounts". The Applicants respectfully traverse this rejection based on the remarks contained herein.

Under § 102, anticipation requires that all the Claim elements appear in a single prior art document. "A Claim is anticipated only if each and every element set forth in the Claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 citing *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2D 1051, 1053 (Fed. Cir. 1987). "The Identical invention must be shown in as complete detail as is contained in the ... Claim." MPEP § 2131 citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2D 1913, 1920 (Fed. Cir. 1989).

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Claim 1 no longer recites "safe and effective amounts", based on the Applicants' previous amendments. Thus, this portion of the rejection has been previously overcome.

The present invention requires in Claim 1 an edible film composition comprising: from about 0.01% to about 15% of a fiber agent selected from the group consisting of indigestible dextrin, purified wood cellulose, psyllium, and mixtures thereof; from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent.

The Barkalow et al. reference does not disclose the Applicants' claimed ranges, i.e. from about 0.01% to about 15% of a fiber agent, from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent. Although some of the ranges overlap, Barkalow does not provide any ranges that completely envelop the Applicants' claimed ranges, nor does Barkalow provide any examples that fall within or meet all of the range limitations of the present claims. When prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute". What constitutes a "sufficient specificity" is fact dependent. See MPEP § 2131.03.

The Applicants assert that Barkalow does not disclose the Applicants' compositions or ranges with sufficient specificity. All of the Applicants' claimed ranges include percentages outside of all of Barkalow's disclosed ranges. Barkalow discloses from 10% to 90% bulk filler, from 10% to 90% film composition, from 0% to 20% plasticizer, and 0.1% to 20% flavor. In contrast, the Applicants' recited ranges include from about 0.01% to about 15% of a fiber agent, from about 2% to about 75% of a film forming agent, from about 0.01% to about 30% of a plasticizing agent, and from about 0.1% to about 60% of a flavoring agent. Therefore, because Barkalow discloses no examples that meet all of the Applicants' claimed ranges, and because all of the Applicants' claimed ranges include percentages outside of all of Barkalow's disclosed ranges, Barkalow does not anticipate

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the present invention or Claims. Since Barkalow et al. does not disclose each and every element of the present application, it cannot as a matter of law anticipate the present application.

The Applicants therefore respectfully request reconsideration and withdrawal of the rejection on this basis.

Rejection Under 35 USC §103(a)

Claims 1-7 and 9-13 have been rejected under 35 USC 103(a) as being unpatentable over Barkalow et al. in view of US Patent No. 5,458,892 to Yatka et al. ("Yatka"). The Examiner states that Barkalow discloses an edible film composition comprising bulk filler agents, film forming agents, plasticizing agents and flavoring agents wherein the bulk fibers may be wood cellulose, the film forming agents are hydroxypropyl methyl cellulose, and that the composition may additionally contain vegetable oils. Ranges for the bulk filler, film forming agent, plasticizer, and flavor are disclosed. No range for surfactant is disclosed. It is disclosed that the composition dissolves rapidly.

The Examiner acknowledges that Barkalow does not disclose indigestible dextrin with the claimed fiber length, or wherein the bulking agent encapsulates the flavoring agent. However, the Examiner asserts that indigestible dextrin was a known and used bulk filler agent in the art.

The Examiner states that Yatka discloses a bulking agent that is indigestible dextrin with the claimed fiber length. In addition, the Examiner asserts that the indigestible dextrin can be dried with flavors to encapsulate the flavor.

Thus, the Examiner asserts that it would have been obvious to use the indigestible dextrin of Yatka as the bulk filling agent of Barkalow, and that one would have been motivated to do so with a reasonable expectation of successfully obtaining the functional edible film of Barkalow.

The Applicants respectfully traverse this rejection based on the remarks contained herein.

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As argued above, Barkalow fails to disclose any of the Applicants' particular ranges, and thus fails to disclose the Applicants' claimed compositions. Barkalow discloses pullulan free edible films. Barkalow discloses that the bulk filler agent can include cellulose polymers such as wood. The wood cellulose of the present invention is purified wood cellulose. These materials are highly purified cellulose and comprise more than 99% dietary fiber. (See Page 5, line 8-12). Barkalow fails to teach or suggest purified wood cellulose and a cellulose polymer such as wood would *not* have the same composition makeup as purified wood cellulose. Thus, purified wood cellulose would not automatically be within the scope of the disclosure of Barkalow. Furthermore, as noted above, Barkalow does not disclose or suggest the purified wood cellulose or an edible film composition comprising: from about 0.01% to about 55% of a fiber agent selected from the group consisting of indigestible dextrin, purified wood cellulose, psyllium, and mixtures thereof; from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent. Barkalow never teaches or suggests from about 0.01% to about 15% of a fiber agent, from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent as described and claimed in the present invention.

Yatka discloses a chewing gum product containing indigestible dextrin. Yatka discloses that is highly preferred to use purified indigestible dextrin, having all of the fermentable components removed. Additionally, Yatka does not teach or suggest the fiber length. Yatka discloses the molecular weight (Column 3, Lines 30-33), the location of specific linkages or bonds (Column 3, lines 5-21), caloric value (Column 3, lines 44-50), and that it is preferable to use a carbohydrate or carbohydrate like food ingredient for chewing gum (Column 1, lines 40-50). The indigestible dextrin in the Yatka reference is being used to provide a bulk sweetener to the chewing gum.

In contrast, the indigestible dextrin of the current invention is used as a source of fiber and film strength. One of ordinary skill in the art would not be motivated based on the disclosure of Yatka to use the indigestible dextrin as a fiber source. Nowhere in Yatka does it teach or suggest that by using the indigestible dextrin that there will be an

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increasing of the film strength of an edible film composition while at the same time maintaining complete and/or rapid film dissolution. Furthermore, Yatka actually teaches against dissolution in general. Chewing gum is not supposed to dissolve. Therefore, one of skill in the art would have been directed away from using indigestible dextrin in compositions designed to dissolve, and in particular, dissolve rapidly. Yatka only provides direction that indigestible dextrin can be used to give improved texture, moisture absorption properties, and shelf life properties to chewing gum. There is no indication in Yatka that indigestible dextrin would be suitable at all for edible film compositions.

Furthermore, even if one were to attempt to combine indigestible dextrin as used by Yatka in a chewing gum with the disclosure of Barkalow, because Barkalow does not provide *any* of the Applicants' claimed ranges, one would certainly not have any expectation of success in arriving at the particular claimed compositions, or have any idea what appropriate amounts or fiber lengths would be if attempting to combine Yatka and Barkalow. As argued above, one of skill in the art would not even be sure indigestible dextrin could be used in edible film compositions.

However, assuming *arguendo* that one having ordinary skill in the art would have combined the disclosures of Barkalow and Yatka, one would still have fallen short of the Applicants' claimed invention only to have arrived perhaps at a pullulan free edible film that contains cellulose polymers such as wood and an indigestible dextrin bulk sweetener that does not contribute to dental caries, or perhaps one would have arrived at a pullulan free chewing gum.

The combination of Barkalow and Yatka does not teach or suggest each and every element of Applicants' presently claimed invention i.e. an edible film composition comprising: from about 0.01% to about 15% of a fiber agent selected from the group consisting of indigestible dextrin, purified wood cellulose, psyllium, and mixtures thereof; from about 2% to about 75% of a film forming agent; from about 0.01% to about 30% of a plasticizing agent; and from about 0.1% to about 60% of a flavoring agent or a film composition that rapidly dissolves in the oral cavity. In addition neither Barkalow

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nor Yatka teaches or suggests wherein the composition has from about 0.001% to about 20% by weight of surfactant.

Accordingly, Claims 1-7, 9-13 are novel and nonobvious over the prior art of record, and the Applicants respectfully request reconsideration and withdrawal of the rejection on this basis.

Double Patenting Rejection

Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-12 of copending Application No. 10/810,939.

The double patenting rejection is provisional, and thus premature, because the asserted conflicting claims have not yet been allowed. Therefore, because the rejection is premature, the Applicants are not filing a terminal disclaimer at this time, but will address the double patenting rejection if the copending claims become allowed.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied documents. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of all pending claims are respectfully requested.

Respectfully submitted,

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